Create and Submit a Repository Application Amendment

Once a repository application has been approved, an amendment must be created to document changes to the application (e.g., changes to repository personnel, sponsors, subject data, etc.). An amendment can be initiated by repository personnel with edit rights listed on the approved application, but it can only be submitted for review by the repository director. After submission, the amendment is locked and no further changes can be made unless requested by a reviewer.

This procedure contains two parts:

Creating a Repository Application Amendment and Submitting a Repository Application Amendment

Creating a Repository Application Amendment

Home Workspace

1. Click Approved to display approved applications.

2. Click the Name of the repository application to view the approved application workspace.

Repository Workspace

3. Click Amendment.

Note: Only one amendment for a Repository Application can be in progress at a time.
Amendment Creation

4. Complete the required field(s) to describe the purpose of the amendment.

5. Click Continue.

Note: A copy of the approved repository application that can be amended will open. The repository application will be assigned an amendment ID number. From that point, the amendment can be saved for completion at a later time.

Amendment

6. Edit any fields that need to be changed in the amendment form.

7. Click Continue to proceed to the next section of the amendment to continue editing.

Note: If you have finished editing the amendment, you can click Exit to return to the amendment workspace.
Amendment Workspace

Note: The amendment is in the state of **AME Pre Submission**.

8. To notify the Repository Director that the amendment is completed, click **Move to Ready to Submit Inbox**.

Note: To open an amendment that is in-progress, click **Edit Application** from the amendment workspace.
Submitting a Repository Application Amendment

Only the Repository Director can submit an application amendment.

Home Workspace

1. On the My Inbox tab, under Require Action by Study Team, click on the Name of the repository application amendment. It should be in the state of AME Pre Submission.

Amendment Workspace

2. Click Edit Application to open and review the amendment.

3. Review and save any changes, if needed. Click Exit to return to the amendment workspace.
Amendment Workspace

4. Click Submit.

Note: The system validates that all required fields are complete. Any errors must be addressed before the amendment can be submitted.

Submit Application Window

5. Read the Repository Director Assurances and click the checkbox confirming that you agree to abide by the assurance statement.

6. Click OK.

Notes:
- The state of the amendment changes to IRB Review, and you are returned to the amendment workspace.
- Once approved, click View Differences in the Repository Application Workspace to see what was changed (not shown here).